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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/602,345	06/23/2003	Andres F. Zuluaga	12258-029001	1603
26161	7590	10/26/2007		
FISH & RICHARDSON PC P.O. BOX 1022 MINNEAPOLIS, MN 55440-1022			EXAMINER MEHTA, PARIKHA SOLANKI	
			ART UNIT 3737	PAPER NUMBER
			MAIL DATE 10/26/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/602,345

Applicant(s)

ZULUAGA ET AL.

Examiner

Parikha S. Mehta

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 August 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5,7-13,20,21,43,44,46-51 and 53-61 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5,7-13,20,21,43,44,46-51 and 53-61 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>9/11/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1 August 2007 has been entered.

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on 11 September was filed after the mailing date of the Request for Continued Examination on 16 August 2007. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Response to Arguments

3. Applicant's arguments with respect to claims 1-5, 7-13, 20, 21, 43, 44, 46-51 and 53-61 have been considered but are moot in view of the new ground(s) of rejection. However, Applicant's arguments challenging the application of Hammerslag (US Patent No. 5,372,587) are still relevant to the currently amended claims. Specifically, Applicant alleges that the combination of Hayes (US Patent No. 4, 967,745) would require the surgeon to "pull on a deflection wire for the entire scanning procedure to maintain contact between the tip of the probe and the arterial wall," and that "[i]n doing so, the surgeon may have difficult pulling on the wire with the appropriate amount of force" (Remarks p. 9). While Examiner admits that this is indeed possible, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. It remains that the invention of Hayes ('745) as modified by Hammerslag ('587) would certainly be capable of "resiliently assuming a preferred shape," and therefore the combination of references still reads on the claimed invention. Furthermore, Examiner respectfully

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points out that the term "resilient" can be broadly interpreted in view of the general definition of the word as set forth by Merriam Webster (<http://www.m-w.com>):

resilient: capable of withstanding shock without permanent deformation or rupture

Accordingly, the question is not whether a surgeon would fatigue of holding the pull wire during the procedure, but whether the probe is capable of withstanding deflection without permanent deformation. As has been previously shown and discussed with Applicant's representative, a pull wire effectively satisfies this limitation.

4. Applicant has failed to adequately respond to the previous double patenting rejection set forth in the prior Office Action. Accordingly, the rejection is maintained and reiterated herein.

Double Patenting

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 1-13, 20, 21, 43, 44 and 46-51 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 10, 11, 15, 17 and 18 of copending Application No. 10/940468. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the instant application are merely broader than those of the co-pending application, and therefore all limitations of the instant claimed invention are present in the conflicting claimed invention.

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This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 53-55 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 53 and 55 recite dependence from claim 52, which is no longer pending in the application. Accordingly, these claims cannot be treated further on the merits and their patentability cannot be evaluated in view of the presented prior art herein.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

10. Claims 1, 2, 5, 7-10, 11, 20, 21, 43, 44, 46-49, and 56-61 are rejected under 35 U.S.C. 102(b) as being anticipated by Hayes et al (US Patent No. 4,967,745), hereinafter Hayes ('745).

Regarding claims 1, 2, 5, 7-10, 11, 21 and 46-49, and 56-61, Hayes ('745) discloses a method and apparatus for spectroscopic analysis of plaque within a blood vessel comprising a probe with one or more optical fibers extending therethrough, an optical shield and lens configured to contact the intraluminal wall at a point at which light exits the coupler and enters the wall, and a light source and detector in optical communication with the optical fiber (Fig. 1, col. 4 lines 40-51 & 59-64). Hayes ('745) shows the probe to have a rounded distal tip and further states that it may be "hemispherical, flat,

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lens-shaped, or of any other shape” (col. 7 lines 65-68). The hemispherical tip of Hayes ('745) is considered “atraumatic” as claimed in the instant application, as it is free of any sharp edges, corners, or any other such protrusions that might be reasonably capable of damaging the vessel wall. The rounded tip and transparent optical shield disclosed by Hayes ('745) together constitute both “an atraumatic light-coupler in contact with the optical fiber, the coupler being configured to atraumatically contact the intraluminal wall at a point at which light exits the atraumatic light-coupler and enter the wall” and a jacket enclosing the fiber as claimed in the instant application. According to this interpretation, a surface of the light coupler is disposed along a side of the probe as recited in claim 59. Hayes ('745) further discloses deflection wires for causing the distal end of the catheter to curve (Figs. 17A-D), which constitutes a probe resiliently assuming a preferred shape as claimed.

Regarding claim 20, Hayes ('745) specifically provides the probe for use with a laser source (col. 7 lines 50-64), and further defines “laser” as a device that produces infrared light (col. 1 lines 17-23).

Regarding claims 21, 43 and 44, Hayes ('745) additionally discloses means and steps for providing the received light to a computer (col. 21 lines 14-21), wherein the computer constitutes a processor as claimed in the instant application.

Claim Rejections - 35 USC § 103

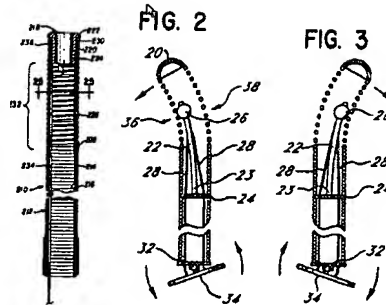
11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hayes ('745) in view of Hammerslag (US Patent No. 5,372,587), hereinafter Hammerslag ('587).

Hayes ('745) substantially teaches all features of the present invention as previously discussed for claim 1. Hayes ('745) does not teach a jacket comprised of wound coil-wire. In the same field of endeavor, Hammerslag ('587) teaches the use of a coiled wire sheath in conjunction with catheters, cannulae, guidewires and the like for the purpose of enhancing steerability of such medical devices (col 1 line 14, Figure 1).

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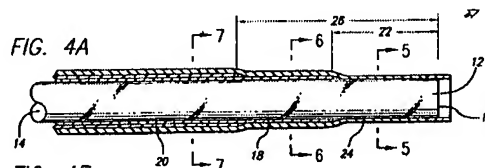


Source: Hammerslag ('587) Figures 1-3

It would have been obvious to one of ordinary skill at the time of invention to modify the probe of Hayes ('745) to further include the wound coil-wire jacket of Hammerslag ('587) to facilitate and improve ease of navigation of the probe through the patient's vasculature, in view of the teachings of Hammerslag ('587).

13. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hayes ('745) in view of Hammerslag ('587) as applied to claim 3 above, and further in view of Derbin (US Patent No. 6,562,021), hereinafter Derbin ('021).

Hayes ('745) and Hammerslag ('587) substantially teach all features of the present invention as previously discussed for claim 3. Neither Hayes ('745) nor Hammerslag ('587) teach that the coil wire of the probe jacket is of variable diameter. In the same field of endeavor, Derbin ('021) teaches the use of a variable-thickness catheter shaft in order to provide variations in stiffness along the length of the catheter, more specifically to make the distal tip more flexible than the rest of the body (Fig 4A).



Source: Derbin ('021) Figure 4a

It would have been obvious to one of ordinary skill in the art at the time of invention to modify the probe of Hayes ('745), previously modified by Hammerslag ('587), to further include a variable-diameter coil-wound jacket so as to improve distal flexibility while also maintaining proximal stiffness during probe navigation, in view of the teachings of Derbin ('021).

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14. Claims 12, 13, 50 and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hayes ('745) in view of Utzinger et al (Fiber optic probes for biomedical optical spectroscopy. *Journal of Biomedical Optics*. 8(1): pp. 121-147. January 2003), hereinafter Utzinger (2003).

Hayes ('745) substantially teaches all features of the present invention as previously discussed for claim 1. Hayes ('745) does not expressly teach an embodiment of the probe wherein the coupler is integral with the optical fiber. In the same field of endeavor, Utzinger (2003) teaches that cleaving and polishing the distal end of an optical fiber to create a beveled or flat end surface creates a coupling surface that is more efficient than a lens coupler (p. 123 ¶ 3). It would have been obvious to one of ordinary skill in the art at the time of invention to modify the probe of Hayes ('745) to omit the separate lens coupler and instead use a cleaved, polished distal end of the optical fiber as the light coupler in order to enhance the coupling efficiency of the probe, in view of the teachings of Utzinger (2003).

Conclusion


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Parikha S. Mehta whose telephone number is 571.272.3248. The examiner can normally be reached on M-F, 8 - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571.272.4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Parikha S. Mehta

Examiner – Art Unit 3737


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